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### The ESRC Centre for Social and Economic Research on Innovation in Genomics (Innogen)

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**The ESRC Centre for Social and Economic Research  
on Innovation in Genomics (Innogen)**

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## 1. Five plus five

Innogen (the UK ESRC Centre for Social and Economic Research on Innovation in Genomics) began its second five-year phase in late 2007. Innogen, a collaboration between the University of Edinburgh and the Open University, began in 2002. It belongs to the ESRC Genomics Network, made up of two other centres: Cesagen and Egenis and the ESRC Genomics Forum. From the beginning, Innogen's aim has been to research the big changes right across the life sciences. We study the new *science* but also the implications for new *technologies* and how genomics and post-genomics might change the life science *industries* – health, crop and animal. Thus, our aim has been to study genomics as an integral part of the life sciences.

From the beginning, it was our premise that the nasty surprises – and also the big prizes – would come from interactions between the three main sets of actors. These are: *innovators* (scientists, technologists, industry); *policy makers* (including government and the emerging new institutions of governance) and *public and stakeholder groups*. Our approach has been to research interactions between all three and our ambition is to carry out research *with* the key actors - innovators, policy makers, public and stakeholder groups - *not just* study them.

Our initial aims in 2002 were to build an internationally respected centre to enable social scientists and the ESRC to take a leading role in (1) policy, (2) public and innovation-related debate on life science issues, and to (3) contribute to the shaping of the life science trajectory from a well-informed, evidence-based position. Those aims remain and, from 2007, we have added that we will “produce theoretically and empirically grounded research that advances the knowledge base in social science and delivers a sound base for decision-making about life science”, focusing on two themes, each comprising two research clusters. The first theme is the evolution of the life science economy (with clusters on new life sciences and innovation and on globalisation). The second theme concerns the governance of innovation in the life sciences (with clusters on governance and regulation; and on conceptualising engagement).

To describe what we have been doing and what we will do in the future, I selectively focus on four big questions, one for each research cluster:

1. “Can big pharma survive new biology?” and, more generally, “Can new discoveries in the life sciences transform human health?”
2. “Can innovation transform global health?”
3. “Can life science be better regulated?” and: “Can changes in the regulation and governance of the life sciences lead to improved human well-being?”
4. “Can we go beyond ‘talking past each other’?” or, “Can we improve governance and engagement?”

These questions (and others) are being tackled by a large number of Innogen researchers and their collaborators around the UK and the World. We have more than fifty researchers (academics and doctoral students) and have also been able to build very important relations with colleagues in many institutions. One key partner at the

University of Edinburgh is the AHRC Script Centre (which edits this journal) with whom we have a range of joint activities.

## **2. Question 1: Can big pharma survive new biology?**

On the *first question* the big pharmaceutical firms do seem, so far, to be surviving new biology. The long-term sectoral dominance of multi-national pharmaceutical companies has been remarkable – the regulation-driven drug discovery pipeline system has endured for half a century, dominated by a few big pharma firms. But the pharmaceutical industry is certainly maturing and it has been getting harder and harder to find new blockbuster drugs. Research and Development (R&D) spending has been rising, but there has been no corresponding increase in the number of drug launches. Our results show that, so far, new biology is beginning to change the industry. But rather than biotechnology start-ups ending the dominance of the big pharmaceutical firms, they have acted to prop the system up.

Small biotech companies, with very few early exceptions, have been unable to break the regulatory hurdle of clinical trials and the massive expense of entry. But they do have knowledge – even if they cannot develop products. Pharmaceutical firms have begun to take advantage of this new knowledge with a range of new corporate strategies. For example, big pharma has moved to outsource R&D to small biotech companies. One example of this is the big increase in R&D strategic partnerships. Big pharma has also accelerated its buying-up of biotech start-ups.

At the same time, we have seen the rise of translational medicine and attempts to build new institutions that link innovation systems to health systems. Innogen provides research-based modules on innovation, risk regulation and governance for the world's first distance education course in translational medicine at Edinburgh. But, so far, we have seen no big social revolution from new genetic, genomic and post-genomic biology.

But our research suggests possible disruptive change in future. We are seeing systems level turbulence – turbulence at many levels – that may make it difficult to control. Briefly:

- Control of the science is changing: not just big pharma, but wide ranging groups of firms, institutes, universities, medical units and partnerships;
- Increased demand for drugs from developing countries and neglected diseases: linked to calls for radical changes in innovation dynamics – calls linked importantly to new money from Gates et al;
- Continued lack of trust in the drug industry; and
- Drugs for small populations, rather than blockbusters.

These changes could lead to changes in the regulatory system and this, in turn, could trigger changes throughout the whole system.

Innogen will be studying these big changes in the coming years. Figure 1 summarises some of our projects. These are focused on science dynamics, technology dynamics and industrial dynamics.

	Examples of projects
Science dynamics	Emergence of systems biology and synthetic biology
Technology dynamics	Translational medicine research collaboration
Industry/innovation dynamics	Erosion of big pharma; drivers of biotech firm innovative performance; regional dynamics and internationalisation

Figure 1: New life sciences and innovation – some projects

### 3. Question 2: Can innovation transform global health?

The *second* question concerns genomics and global health. Here we focus on two issues: “catch-up” and global health and agricultural innovation partnerships. We have comprehensive results on the catch-up of industrially developing countries, like China, India, Brazil and Argentina, as well as on smaller countries in Africa and Asia. Some countries like Argentina, India, Brazil and China, are rapidly increasing capabilities, albeit from a low base. For example, there is a significant globalisation of clinical trial sites in Eastern Europe, Latin America and Asia. Obviously, low cost is one of several factors which accounts for this, but our results show growth in capabilities in the global south. The use of the clinical trials example (rather than, say, patent data), is to focus not just on the science but also on how new institutional systems for global health innovation and product development go beyond science and its application.

The Innogen team around Joanna Chataway is the first to research global health public-private partnerships (PPPs) as systems of global governance that integrate health systems with innovation systems. Until now, these themes have been weakly connected. New institutions, like the International Aids Vaccine Initiative (IAVI), have been established in an attempt to deal with this gap. Figure 2 summarises some of our ongoing projects in this research cluster.

Our studies highlight the importance of partnerships for integrating international science-based initiatives with local realities, local involvement and learning. We found that the IAVI has made a contribution to capacity building in genomics and associated areas in many developing countries. For example, Rwanda, Kenya and Uganda have developed centres for vaccine clinical trials. The IAVI is, we argue, a potential nexus of innovation, advocacy and health development.

Overall, then, our answer to the second question is that new governance systems for global disease innovation are indeed beginning to change the global health environment. We may be witnessing a realignment of clinical practice, lab research and biomedical application and a change from a drug pipeline innovation system to a broader health-based system.

Global health technology networks (access, inclusion)
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Global health public-private partnerships as systems of global governance
Institutional transformation of the international agricultural system
Innovation in pharma and equity in health

Figure 2: “Can innovation transform global health?” – some projects

#### **4. Question 3: Can life science be better regulated?**

The simple third question entails further complex and serious questions such as “how can policy and regulatory systems keep pace with rapidly evolving developments like stem cells, genetic databases and synthetic biology?” On the one hand, there are increasingly requirements and public pressure for strong government and good evidence-bases for policy decisions. On the other, there are demands for a greater degree of stakeholder engagement. Is this leading to complexities that cannot be resolved? In this area of increasing complexity, can society tailor the necessary public governance of innovative technology (and its risks) whilst fostering innovation?

Our initial research on these topics, begun twenty years ago, focused on decision-making concerning agricultural pesticides and genetically-modified (GM) crops and on the emergence of precautionary regulation. At Innogen, we have broadened our foci to look now at the relationship between regulation and governance. Cathie Lyall and colleagues are presently co-editing a book *Limits to Governance in the Life Sciences*, which will offer a constructive critique of the new governance agenda for science and technology from a range of perspectives.

Figure 3 gives other examples of our current research. We have very productive links with the AHRC Script centre including research on intellectual property and public goods, and on law-making practices in developing countries. Some countries are adopting regulation of life sciences, including Argentina. We are collaborating with Argentinian research colleagues, regulators and policy makers to study the construction of new regulatory frameworks. More generally, we are expanding our research into risk regulation in the life sciences.

Multi-level governance and its limitations
Assessing democratic governance
Governing identity transformation
Law making practices for new life sciences
Intellectual property and public interest
Towards ‘smart’ regulation

Figure 3: Governance and regulation – some projects

### 5. Question 4: Can we get beyond talking past each other?

Our fourth question concerns engagement with genomics. On this question, we have tried to look for novel ways of getting beyond ‘talking past each other’, with research on: stem cell donation; families and genetic databases and reconciling patient rights and the public interest (see Figure 4). We work with Generation Scotland and are part of the successful £1.2m bid for a Beacon of Public Engagement Beltane.

Our research on UK farmers’ experiences of GM crops fills a gap since, surprisingly, farmers have been relatively ignored in the GM crop debate. Farmers are critical that they were not consulted on the design of the GM trials and how outcomes were to be reported. They felt that their experience and skills were not called on in the debates. Thus, even a relatively well-supported engagement initiative, on an issue which was previously a disaster for engagement, was not seen as useful by all stakeholders.

More generally, the research of Robin Williams has suggested we need to step back and take a critical look at the outcomes of engagement activities. Attempts to govern and regulate science and technology in the very early stages of its shaping may not succeed in facilitating better outcomes, given the unpredictability of innovation pathways. It may even be counter-productive by closing down options too early.

So our research on engagement has aimed to understand these complexities in order to improve future engagement, to get beyond ‘talking past each other’. This is a major theme for our next five years as we continue on our journey.

Generation Scotland (biobanks and public consultation)
Social dynamics of public engagement in stem cells
Patient expertise and engagement
Values and interests in stakeholder engagement

Figure 4: Conceptualising Engagement

To summarise, our research has shown that the increasing strains in health innovation cannot be analysed just by studying the science. Social research on how biology is changing drug innovation systems, health markets and policies, and, particularly, governance and regulatory institutions is needed.